STATE OF KANSAS
KANSAS PHARMACY BOARD

NOTICE OF PUBLIC HEARING ON PROPOSED ADMINISTRATIVE REGULATION

A public hearing will be conducted at 9:00 a.m., on the 4th day of March, 2009, at the KU School of Pharmacy, 2056 Malott Hall, Lawrence, Kansas 66045, to consider the addition of K.A.R. 68-19-1 of the Kansas Pharmacy Board.

This 60-day notice of the public hearing shall constitute a public comment period for the purpose of receiving written public comments on the proposed K.A.R. 68-19-1. All parties may submit written comments prior to the hearing to the Executive Secretary of the Kansas Pharmacy Board, Debra Billingsley, pharmacy@pharmacy.ks.gov or Landon State Office Building, 900 SW Jackson, Room 560, Topeka, Kansas 66612-1231. All interested parties will be given a reasonable opportunity to present their views orally on the amendment of the regulation during the hearing. In order to give all parties an opportunity to present their views, it may be necessary to request each participant to limit any oral presentation to five minutes.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the regulation and economic impact statement in an accessible format. Requests for accommodation to participate in the hearing should be made at least five working days in advance of the hearing by contacting the Kansas Pharmacy Board, Landon State Office Building, 900 SW Jackson, Room 560, Topeka, Kansas 66612-1231, (785) 296-4056. Handicapped parking is located on the west and north sides of the building, and the north entrance to the building is accessible to individuals with disabilities.

The regulation is proposed for addition. A summary of the regulation is as follows:

K.A.R. 68-19-1. Continuous Quality Assurance Programs. This regulation identifies the minimum requirement a pharmacy's continuous quality improvement program shall meet.

Copies of the regulation and the economic impact statement may be obtained from the Kansas Pharmacy Board, Landon State Office Building, 900 SW Jackson, Room 560, Topeka, Kansas 66612-1231, (785) 296-4056, or by accessing the Board's website at http://www.kansas.gov/pharmacy/proposedregs.html.

Debra Billingsley
Executive Secretary

STATE OF KANSAS
KANSAS PHARMACY BOARD

ECONOMIC IMPACT STATEMENT

Pursuant to K.S.A. 77-416(b), the Kansas Pharmacy Board submits the following description of the economic impact of K.A.R. 68-19-1.

1. **Summary of Proposed Regulation, Including Its Purpose.** K.A.R. 68-19-1 is a new regulation that establishes the minimum requirements for a pharmacy's continuous quality improvement (CQI) program. These requirements include quarterly meetings with the pharmacist-in-charge present at each meeting. During each quarterly meeting, the pharmacy shall review all incident reports (which are required by K.A.R. 68-7-12b), establish steps taken or to be taken to prevent a recurrence of the incident, and create a report of the meeting. A pharmacy's CQI program is intended to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent recurrence of the error.

2. **Reason or Reasons the Proposed Regulation is Required, Including Whether the Regulation is Mandated by Federal Law.** In 2008, the Kansas Legislature passed, and Governor Sebelius approved, the prescription monitoring program act (the "Act"). *See* L. 2008, ch. 104. As part of the Act, the Kansas Pharmacy Board was given the authority to promulgate administrative rules and regulations regarding the functions and recordkeeping of a pharmacy continuous quality improvement (CQI) program. *See* L. 2008, ch. 104, § 16. This regulation, therefore, is not mandated by federal laws.

3. **Anticipated Economic Impact upon the Kansas Board of Pharmacy, Pharmacists, Pharmacy Technicians, Small Employers, and Others.** No new costs will be borne by the Kansas Board of Pharmacy or patients. While the Board will incur additional duties

to ensure that each pharmacy has a CQI quarterly report and remains in compliance with the regulation, the enforcement responsibilities will be absorbed in the current duties of the Board and will have no fiscal impact. It is anticipated that each pharmacy, some of which may be classified as small employers, will incur additional costs related to the establishment and implementation of the pharmacy's CQI program. As previously noted, each pharmacy will have to conduct a quarterly review of all the incident reports, which are required by K.A.R. 68-7-12b. The cost of each pharmacy's CQI program, however, is projected to be highly variable and depends heavily on the number of pharmacy staff that must be trained regarding the CQI program, the time it will take each pharmacy to establish and monitor the CQI program, including the development of workflow processes designed to prevent errors, and the number of incident reports that must be reviewed at each quarterly meeting. The varying requirements for each pharmacy could have an economic impact on pharmacists and pharmacy technicians who, by virtue of their compliance with the pharmacy's CQI program, may be required to spend more time working in the pharmacy, particularly during the quarterly CQI meeting.

4. **Less Costly or Intrusive Methods That Were Considered.** The Board is not aware of any less costly or less intrusive methods to achieve the stated purposes and thus none were considered.

5. **Environmental Benefit Statement.** This is not a proposed environmental regulation.

Article 19 - Continuous Quality Assurance Programs

68-19-1. Minimum program requirements. Each pharmacy's continuous quality improvement program shall meet the following minimum requirements:

(a) Meet at least once each quarter of each calendar year;

(b) have the pharmacy's pharmacist in charge in attendance at each meeting; and

(c) perform the following during each meeting:

(1) Review all incident reports generated for each reportable event associated with that pharmacy since the last quarterly meeting;

(2) for each incident report reviewed, establish the steps taken or to be taken to prevent a recurrence of the incident; and

(3) create a report of the meeting, including at least the following information:

(A) A list of the persons in attendance;

(B) a list of the incident reports reviewed; and

(C) a description of the steps taken or to be taken to prevent a recurrence of each incident reviewed. (Authorized by and implementing L. 2008, ch. 104, §16; effective P-_____.)

ATTORNEY GENERAL

SEP 3 0 2008

APPROVED BY

DEPT. OF ADMINISTRATION

SEP 2 5 2008

APPROVED